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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,521	02/11/2002	Wen-Fu T. Lai	10627-004001	5316
26161	7590	10/06/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/073,521	LAI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Claims examined on the merits are 1-24 which are all claims in the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

5 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claim 1-3, 5-7, 9-13, 15-18, 20, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the randomly rewound types I and II collagen when partially digested, does not reasonably provide enablement for the collagens when not partially digested. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

20 In view of the description in the specification of how the randomly rewound collagens are prepared, it appears preparing the collagens requires partial digestion. No method is described of preparing the collagens without partial digestion.

***Claim Rejections - 35 USC § 112***

25 The following is a quotation of the second paragraph of 35 U.S.C. 112:

30 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the  
5 invention.

The claims are unclear as to when in the method the cells and substrate are placed in the rotating and oscillating vessel. Are the cells in the vessel during growing or at some other time in the method?

10 ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any  
25 evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art  
30 under 35 U.S.C. 103(a).

Claims 1-6, 8, 9 and 11-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al (5,876,444) in view of Muller et al (6,623,963 B1) and Mansmann (6,530,956 B1).

5 The claims are drawn to producing a cartilage implant by growing chondrocytes or mesenchymal stem cells in a substrate containing randomly rewound  $\alpha$ -helical monomers of type I collagen. Randomly rewound  $\alpha$ -helical monomers of type II collagen may also be in the substrate. Also claimed is the resulting implant.

10 Lai et al disclose using randomly rewound  $\alpha$ -helical monomers of type I collagen as an implant for tissue repair. The collagen is produced by partial digestion.

Muller et al disclose a cellular matrix for implanting to repair tissue. The implant contains a reconstituted type II collagen that has been produced by a method that involves partial digestion (Example 15 I). The matrix may be seeded with cells such as chondrocytes prior to implanting (col 6, lines 1-44) to repair cartilage defects.

Mansmann disclose a scaffold for tissue repair. The scaffold may be made of collagen (col 8, line 38 and col 14, line 30), and may be seeded with cells (col 16, lines 1-10) such as chondrocytes.

20 It would have been obvious to seed the collagen implant of Lai et al with chondrocytes as suggested by Muller et al and Mansmann disclosing seeding collagen implants with chondrocytes prior to implanting. Seeding with the cells would have been expected to provide cells present when implanted to produce repair tissue sooner.

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It would have been further obvious to combine the type II collagen of Muller et al with the type I of Lai et al to obtain the properties of both together. The method of producing the type II collagen of Muller et al appears to result in randomly rewound  $\alpha$ -helical monomers of type  
5 II collagen. Obtaining the collagens and cells from different animal sources as in claims 6, 9, 21, 23 and 24 would have been obvious since Muller et al and Mansmann use different animal sources for the cells and collagen.

Claims 7 and 10 are free of the prior art.

10 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful,  
15 the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose  
20 telephone number is 703-308-0196.



David M. Naff  
Primary Examiner  
Art Unit 1651